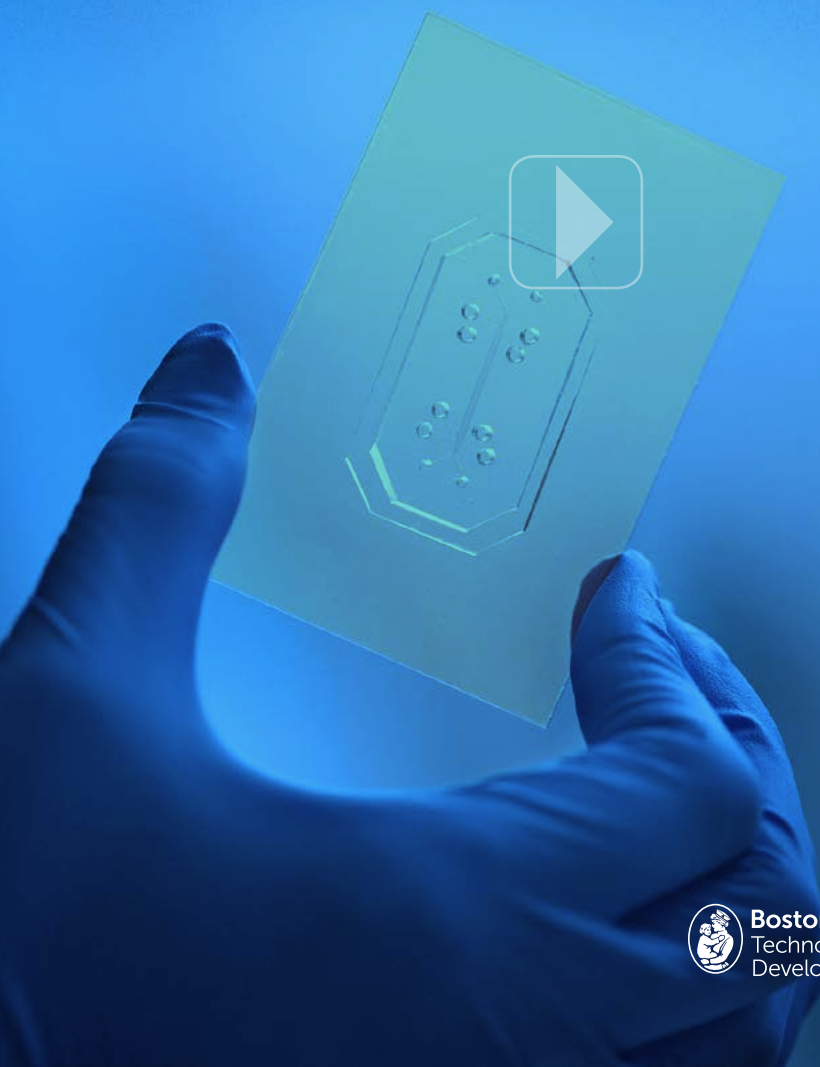


Inventor's Guide



Boston Children's Hospital
Technology & Innovation
Development Office

ABOUT THE INVENTOR'S GUIDE

This guide aims to help inventors, innovators, scientists and clinicians at Boston Children's Hospital navigate the hospital's innovation development ecosystem — from invention/discovery through commercialization. Organized to answer frequently asked questions, the guide outlines the essential elements of technology evaluation, technology development, startup formation and licensing. The guide also covers contractual relationships with companies, such as industry-sponsored research and material transfer agreements. Finally, it provides a broad overview of the Technology and Innovation Development Office and its services.

*We would like to thank the
University of Michigan Technology Transfer Office
for their permission to use this content.*

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The mission of the Technology and Innovation Development Office (TIDO) is to maximize the impact of Boston Children's innovations on patient health while enhancing the research endeavor.



1.

OVERVIEW

Why does Boston Children's encourage employees to participate in the innovation process?

Hospital researchers and innovators conduct cutting-edge scientific research that can benefit society, combat diseases, save lives and improve the quality of care for children and adults. For many of these discoveries to have the broadest impact, they must be translated into products and services. Developing new solutions to address unmet medical needs and improving the well-being of patients can bring deep personal satisfaction and fulfillment, recognition among peers and potential financial rewards.

How does an invention become a product that can benefit the public?

The path from a research discovery or invention to a product on the market can be lengthy and complex. Developing new treatments, diagnostic tests and medical devices can take many years and hefty financial investment. For health care IT innovations, the path to market may be comparatively shorter. Most inventions and innovations developed in academic settings like Boston Children's are at the earliest stage of the commercialization pathway. They require tremendous investment of time and money from a commercial partner to optimize the discovery, scale it for commercial production, conduct clinical trials, obtain regulatory approval, and ultimately manufacture and sell the product. TIDO protects Boston Children's intellectual assets and seeks the best commercial partners to bring our discoveries to the market to improve patient health.

Once TIDO identifies an appropriate commercial partner, the invention is typically transferred through a license agreement in which the hospital grants its rights in the defined technology to the licensee for a stated period of time. The licensee can be a startup or established company and must commit to product development milestones and agree to take on payment obligations. Pursuant to Boston Children's Intellectual Property Policy, any revenue Boston Children's receives under an IP license is shared with the inventors*, Boston Children's endowment, the departments/programs and laboratories where the research was conducted, and TIDO. These funds are used to support further research and education, and Boston Children's innovation ecosystem.

Who owns inventions created by academic researchers and innovators and why?

The United States Bayh-Dole Act of 1980 allows universities and other non-profit institutions to own rights to discoveries resulting from federally-funded research, provided they meet certain obligations. Obligations include making efforts to protect (when appropriate) and commercialize the discoveries, giving preference to small businesses (when they demonstrate sufficient capability) and sharing any resulting revenues with the inventors. The Act is credited with stimulating interest in tech transfer activities and generating increased research, commercialization, educational opportunities and economic development in the U.S.

* Throughout this manual, unless specifically described otherwise, the term "inventor" includes individuals listed on a patent as well as contributors who have shared in creating the value of IP that is not patented.

2.

THE COMMERCIALIZATION PROCESS

How do I start the process for my invention?

We encourage you to contact TIDO during your early research activities to discuss the commercial potential of your research. Our staff are trained to assist you with questions related to marketability, funding and development, commercialization, patenting and other IP protections, starting a company, Boston Children's policies and procedures, and much more. We will assign you a licensing manager who is supported by our internal IP and contracting specialists, marketing and business development professionals, and Boston Children's Technology Development Fund principals.

What is my role as an inventor?

- » When you think you have created an invention or discovered something unique with commercial or research value, you should first complete TIDO's invention disclosure form. Note any companies and contacts you believe might be interested in your invention.
- » Contact TIDO before having discussions with anyone outside of Boston Children's, including companies or the press, to avoid losing any patent rights and hindering the opportunity to market your invention.
- » Respond to TIDO and outside patent counsel requests. While some aspects of the patent and licensing process may require significant time on your part, we will strive to use your valuable time efficiently.
- » Keep TIDO informed of upcoming publications or interactions with companies related to your invention. In some cases, a [confidential disclosure agreement](#) may need to be put in place before a discussion with the company to protect Boston Children's patent rights.

How long does commercialization take?

The process of developing the invention, protecting the technology and finding the right commercial partner may take months to years to complete, depending on the stage of the technology, potential market, competition, amount of development resources and work needed, and willingness of the commercial partner.

Steps to commercialization

Note that these steps can vary in sequence and can occur simultaneously.

1. Research and innovation

The commercialization process begins when Boston Children's clinical, research or support staff invent, discover, create, develop or find a solution that could improve patient health. Inventions include medical devices, diagnostics, health care IT, therapeutics, vaccines, and research and product development tools.

2. Pre-disclosure early discussions

To maximize the commercial potential of your research efforts, we encourage you to talk to TIDO early. We can provide guidance with respect to the disclosure and evaluation process, IP protection and steps towards commercialization.

3. Invention disclosure

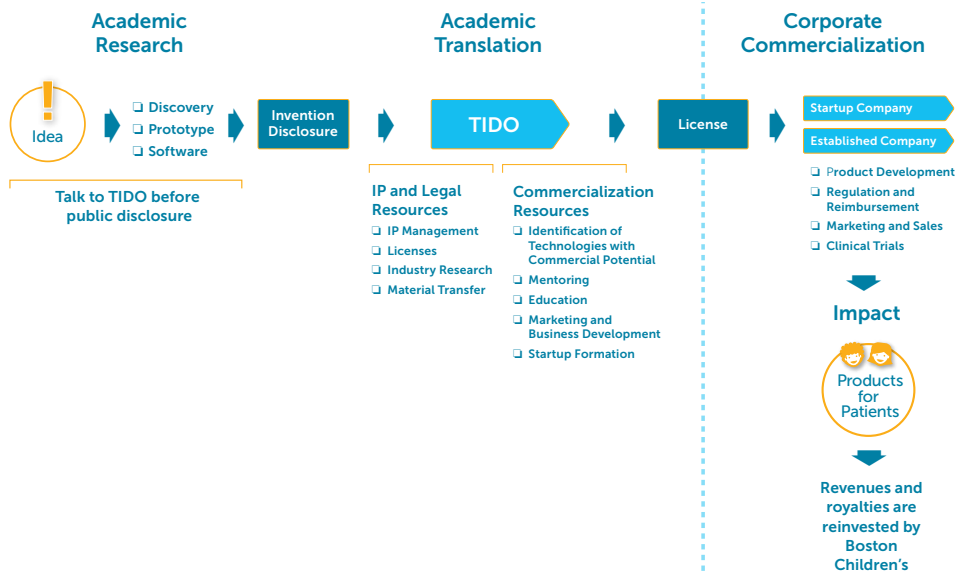
Once you think you have a scientific discovery or clinical innovation that may have commercial potential and could improve patient care, submit an invention disclosure to TIDO so we can create a formal record and begin a formal assessment of your invention.

An invention disclosure is a confidential document and all interactions with TIDO are confidential.

4. Assessment

TIDO assesses the technology's commercial potential and technical challenges, and explores IP options. If a technology has commercial potential, we will work with the inventors to determine the best path forward. This evaluation process may lead to a broadening or refinement of the invention and will guide our marketing and licensing strategy.

Roadmap to Commercialization



R & D Resources

TIDO Technology Development Fund

Other Boston Children's Translational Funding and Resources: IDHA, TRP, SIMPeds

External Funding and Resources: Industry, Foundation, Government, etc.

Corporate Investment in Product Development

THE COMMERCIALIZATION PROCESS

5. Intellectual property (IP) protection

TIDO will evaluate whether IP protection is likely to increase an invention's value and odds of commercial success, including attracting investment from a commercial partner. If we decide to file a patent, TIDO covers the costs. We work closely with the inventors and engage IP attorneys from reputable law firms to craft the strongest application. Once an application has been filed, it typically requires several years and tens of thousands of dollars to obtain a U.S. patent and even more time and money for a foreign patent. Other IP protection methods include copyright and trademarks.

6. Technology Development Fund awards and services

The Technology Development Fund (TDF), run by TIDO, seeks to bridge the gap between early-stage academic technologies arising from Boston Children's laboratories and clinics into the late-stage opportunities sought by licensees and investors. TDF provides funding to advance the development of select hospital technologies, facilitates access to industry mentors and product development leaders, and establishes collaborations with contract research organizations for technical support.

7. Business development and marketing

TIDO's Business Development and Marketing team works to build awareness of Boston Children's and its technologies through relationships with industry and venture capital partners. The team works with inventors to find partners at existing companies or to form startups around inventions. Your active involvement can help to find the right partnership and speed this process.

8. Sponsored research and collaborations

TIDO's Business Development and Marketing team connects Boston Children's investigators and clinicians with industry partners at all stages of research, development, and pre-clinical and clinical investigation. We pair researchers with groups that have similar R&D objectives and complementary resources to form successful collaborations. TIDO negotiates all agreements that govern these

relationships.

9. Forming a startup or partnering with an established company

If creating a new company is the optimal commercialization path, TIDO will help you plan the company, develop a business plan, identify sources of funding and connect with potential management professionals. Alternatively, if working with an established company is the right approach, TIDO will help identify the best partner and will negotiate an appropriate license agreement.

10. Licensing

A license agreement is a written contract between Boston Children's and a company that transfers the hospital's IP rights to the company for product development and commercialization. Licensing agreements include financial terms, such as royalty payments, and terms to ensure that the company will commit to developing and commercializing your technology. If a company wishes to evaluate a technology before fully committing to a license agreement, we will often enter into an option agreement, giving the company a limited exclusive period to explore the business opportunity. Startup companies often use an option agreement to raise funding before licensing the inventions.

11. Licensee product development and licensing revenue

TIDO monitors the licensing partner's progress to ensure that the licensed technology is developed and commercialized effectively. Any revenues generated from the agreement are distributed according to Boston Children's Intellectual Property Policy.



3.

RESEARCH CONSIDERATIONS AND MATERIAL TRANSFER AGREEMENTS

How are patent rights affected by the use of material from another lab in my research?

When receiving materials from other labs, both academic and industrial, we usually enter into a Material Transfer Agreement (MTA) with the other party. An MTA will cover any restrictions on the use of the material and address conditions that may impact the ownership and licensing rights of your research results. When seeking to acquire material from outside of Boston Children's, please download and fill out the incoming MTA questionnaire on childrensinnovations.org and submit it to MTA@childrens.harvard.edu. TIDO will keep you informed throughout the MTA negotiation process and will return a fully-executed copy of the MTA for your records.

Will I be able to share materials related to an invention with other researchers?

Yes. However, it is important to document the items that are to be shared and any restrictions on the recipients' use of the material. If you wish to send materials to an outside collaborator, TIDO will prepare an outgoing MTA for this purpose. Please refer to TIDO's website for the MTA instructions.

What rights does an industry research sponsor have to any discoveries from my research?

When a company sponsors research in your lab, TIDO will negotiate a corporate-sponsored research agreement that will specify any rights the company may have to IP coming out of your research. Boston Children's retains ownership of patent rights and other IP resulting from sponsored research. However, the sponsor may have rights to obtain a license to the defined and expected outcomes of the research.

Often, an Option Clause in the contract allows the sponsor a defined amount of time to negotiate a license for any IP rights developed through the funded research. Even so, the sponsor will not have contractual rights to discoveries that are clearly outside the scope of the research. Therefore, it is important to define the scope of work within a corporate-sponsored research agreement.

Material Transfer Agreement (MTA)

Get instructions and forms at childrensinnovations.org or email mta@childrens.harvard.edu.

What about consulting with industry?

If you are faculty, you may consult for up to 20 percent of your professional time, provided that your chief, program director or vice president approves. You must provide the consulting agreement to the Office of General Counsel, who will review it and attach Boston Children's mandatory consulting terms to protect our IP. The Office of General Counsel does not provide personal advice on consulting agreements, so you may wish to have your own personal lawyer review such agreements. Agreements for speaking engagements under \$5,000 and expert witness testimony do not need review by the Office of General Counsel. If you would like guidance on whether your consulting requires prior approval and review, please discuss with Boston Children's Compliance Office.

4.

INVENTION DISCLOSURES

What is an invention disclosure?

An invention disclosure is a written description of your invention or technology that you provide to TIDO. The disclosure starts a process that may lead to the commercialization of your technology. The invention disclosure should describe the invention in detail and list all the contributors and funding sources that supported the work. This helps TIDO assess the invention for IP protection, marketing and commercialization. Please note that a disclosure to TIDO is confidential and is not a public disclosure.

Why should I submit an invention disclosure?

Your completed invention disclosure form serves as the formal record of your invention under the Boston Children's Intellectual Property Policy. In addition, federal and industry grants generally require that you disclose all inventions. If federal funds were used to support your research, Boston Children's is required to report inventions to the federal sponsoring agency. Disclosing to TIDO does not by itself protect the invention, but is an important starting point.

How do I submit an invention disclosure?

You can download an invention disclosure form and simple instructions from [childrensinnovations.org](https://www.childrensinnovations.org). New invention disclosures are assigned to a [licensing manager](#) who covers your department.

"IMPROVING PATIENTS' LIVES DRIVES OUR WORK AT TIDO. We do this by building partnerships with industry to translate the incredible discoveries being made by Boston Children's innovative researchers and clinicians into treatments and services that improve patient health. I hope this guide will encourage you to explore the commercial potential of your innovations by working with TIDO."

— **Irene Abrams**
Senior Director, TIDO

When should I disclose my invention?

Please inform TIDO as soon as you believe you have created an invention and prior to making any public statements describing the invention. This includes external presentations or poster sessions, meetings with companies or publications. Don't worry that it might be too early to disclose; your TIDO licensing manager will have a discussion with you and let you know whether the invention needs more work before entering our process. By disclosing to us early, and more importantly prior to making any public statements describing the invention, you give your invention the best chance of protection and commercialization.

Can I publish the results of my research and still protect the commercial value of my invention?

Yes, once a patent application has been filed. Public disclosure of your invention may limit your patent rights. We recommend that you submit an invention disclosure well before communicating about your invention to people outside of Boston Children's. Be sure to inform your TIDO licensing manager at least one month before any presentation, lecture, poster, abstract, website or print description, blog, media interview, research proposal submission, dissertation/master's thesis, journal publication (including online in advance of print) or other public presentation.

Should I disclose research materials or tools?

Yes, if your new tools would benefit others and you are interested in providing them to academic researchers and companies. Typically, research tools include materials such as antibodies, vectors, plasmids, cell lines and mice. Most research tools do not necessarily need patent protection to be licensed to commercial third parties or to generate revenue for your laboratory. TIDO will work with you to develop the appropriate licensing and distribution strategy for your tools.

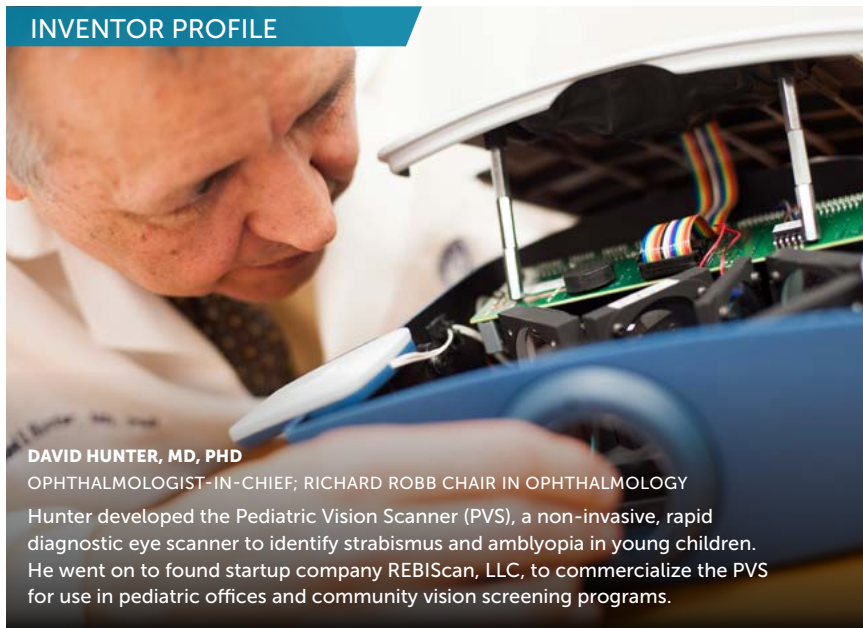
Who is considered an inventor on an invention disclosure?

Generally, an inventor is an individual who has made a contribution to the conception of the invention and its reduction to practice. U.S. patent laws have strict definitions of inventorship, and the standard for inventorship on a patent is much higher than that for authorship on a paper. Inventorship must be listed correctly on a patent or its validity could be in question. If necessary, TIDO will work with you and outside counsel to determine who is an inventor.

I'm collaborating with colleagues at another institution and we have a valuable invention. What should we do?

Disclose your invention to TIDO and list your collaborators. A TIDO representative will meet with you to evaluate the invention and your contribution to it. If we believe that persons from other institutions are inventors, TIDO will work with the technology transfer office of the other institution to jointly manage the invention. Typically, a joint invention agreement is established that defines the rights and responsibilities of each institution, including the sharing of patent costs and revenue.

INVENTOR PROFILE



DAVID HUNTER, MD, PHD

OPHTHALMOLOGIST-IN-CHIEF; RICHARD ROBB CHAIR IN OPHTHALMOLOGY

Hunter developed the Pediatric Vision Scanner (PVS), a non-invasive, rapid diagnostic eye scanner to identify strabismus and amblyopia in young children. He went on to found startup company REBIScan, LLC, to commercialize the PVS for use in pediatric offices and community vision screening programs.

5.

OWNERSHIP OF INTELLECTUAL PROPERTY

What is intellectual property?

Intellectual property (IP) is defined in Boston Children's Intellectual Property Policy and includes all inventions, patents and copyrightable works such as scholarly works, books, data, photos, drawings, diagrams, web content, videos, educational materials, software and mobile apps.

Who owns IP that I create?

Boston Children's owns the IP if your invention is based on an activity supported in whole or in part by Boston Children's funds, personnel, facilities, materials or other resources, or by outside funds or resources administered by Boston Children's (such as a foundation or NIH grant). The same is true if the invention is related to your responsibilities at Boston Children's. There are certain exceptions for creative works such as publications. In addition, if you have joint academic appointments, we ask that you disclose any other IP obligations to TIDO so that we may work with the other institution to sort out any IP ownership questions. Please bring any questions about ownership of IP to TIDO for clarification.

What is Boston Children's policy on ownership of inventions?

Boston Children's full Intellectual Property Policy and guidance documents are found at childrensinnovations.org.

6.

ASSESSMENT OF AN INVENTION DISCLOSURE

How does Boston Children's assess invention disclosures?

Licensing managers at TIDO examine each invention disclosure for the novelty of the invention, patentability, marketability of the potential products or services, size and growth potential of the relevant market, time and money required for further development, pre-existing rights associated with the IP and potential competitors. This assessment may also include consideration of whether the IP can be the basis for a new startup company.

If the inventors believe that all IP should be licensed non-exclusively for the public good, will Boston Children's honor our request?

TIDO will work with you to develop the appropriate licensing strategy for your invention. Some technologies lend themselves to non-exclusive licensing (licensing to multiple third parties), while others will only reach the marketplace, and therefore the public, if they are licensed on an exclusive basis. The licensing strategy will be determined by our assessment of which approach will be the most beneficial for the general public, consistent with governmental or institutional policies and other obligations.

How do we decide whether to commercialize with a traditional or an open-source license for software?

Generally, TIDO supports open-source licensing for the benefit of the general public. TIDO will work with you to evaluate the appropriate open-source license and strategy for dissemination.

INVENTOR PROFILE



JOHN BROWNSTEIN, PHD
CHIEF INNOVATION OFFICER

The HealthMap website parses data from Internet and social media to identify disease outbreaks in real-time. The technology was licensed to Epidemico, which was acquired by Booz Allen Hamilton.

7.

PATENTS AND OTHER LEGAL PROTECTIONS

What is a patent?

A patent is a legal document that gives the holder the right, for a limited term, to exclude others from making, using, selling, offering to sell or importing the patented invention. Patents are economic development tools: they incentivize inventors to publish their inventions in exchange for a limited-term monopoly. Most patents are published and you can find many examples on [uspto.gov](https://www.uspto.gov) or [Google Patents](https://patents.google.com).

What type of subject matter can be patented?

Patentable subject matter is defined by law and generally includes processes, machines, compositions of matter, articles, some computer programs and algorithms, and methods (including methods of making compositions, making articles and even performing business). Certain matters are not patentable, such as laws of nature and mental processes. Recent court decisions have raised patentability doubts for some software and business methods, DNA and other naturally-occurring discoveries, and diagnostic assays that rely on correlation between a disease and parameters in the body.

Search a patent
» [uspto.gov](https://www.uspto.gov)
» patents.google.com

What is the definition of an inventor on a patent and who determines this?

Under U.S. law, an inventor is a person who contributes to the conception of the ideas in the patent claims of a patent application. An employer or person who only furnishes money to build or practice an invention is not an inventor. Inventorship is a legal issue and disagreements about inventorship may require an intricate legal determination by the patent attorney prosecuting the application.

Who is responsible for patenting my invention?

If TIDO decides to file a patent application on your invention, TIDO will engage a patent attorney to draft the application. The patent attorney will work closely with the inventors in drafting the patent applications and in subsequent interactions with the patent office. TIDO oversees the patent prosecution process on behalf of the inventors and covers the costs of patenting.

What is the patenting process?

Patent applications are drafted by a patent attorney in close collaboration with the inventors. The patent attorney will ask you questions about inventorship of the application claims and will ask you to review the application before it is filed. At the time of the filing, the patent attorney will ask the inventor(s) to sign an Inventor's Declaration and an Assignment, which assigns the patent to Boston Children's in accordance with Boston Children's Intellectual Property Policy. The U.S. Patent and Trademark Office (USPTO) will review the application to determine whether the invention is patentable as is (very unusual) or needs to be modified to conform with patent law. The patent attorney, again working closely with the inventors, will draft responses to the patent office's concerns. These steps, called Office Action and Response to Office Action, are often repeated many times until the USPTO, the patent attorney, the inventor(s) and Boston Children's agree on the scope of the patent. Once the scope is agreed upon, the patent will be issued. Patent applications are confidential until the USPTO publishes them 18 months after the initial filing. The entire patent prosecution process will typically take three to six years.

What is the difference between a provisional patent application and a regular or utility patent application?

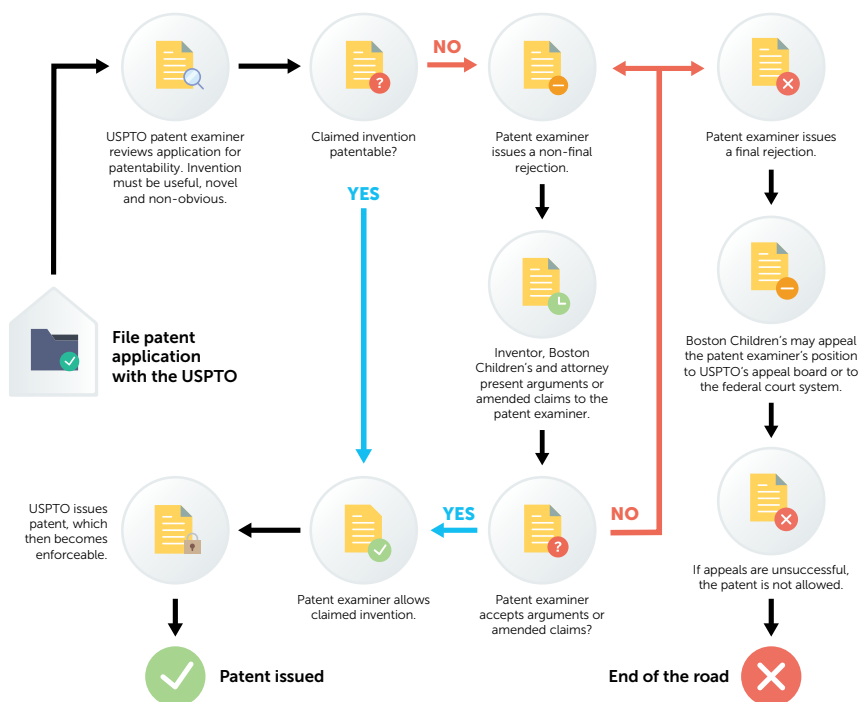
U.S. provisional patent applications are not examined and are a one-year "placeholder" until a regular U.S. application and related foreign applications must be filed. Provisional patent applications have a number of benefits, such as providing an additional year of patent protection and establishing a priority date. They also have fewer filing requirements than a regular U.S. application. However, a provisional patent is only as strong as the material that is adequately described and enabled. As a result, the patent attorney often needs your assistance when a provisional patent is filed.

What's different about foreign patent protection?

You must file patents in each country in which you want patent protection, following each country's patent laws. Fortunately, most countries are party to the Patent Cooperation Treaty (PCT), described below.

The Patent Process

To preserve patent rights internationally, and in most cases in the U.S., patent filing must occur prior to any publication or public disclosure.



Courtesy of Harvard OTD. © President and Fellows of Harvard College.

What is a PCT patent application?

Although an international patent does not exist, the Patent Cooperation Treaty (PCT) is an international agreement that provides a streamlined patent-filing procedure for most industrialized nations. For U.S. applicants, a PCT application is generally filed one year after submission of the corresponding U.S. application (either provisional or regular). The PCT application must later be filed in the national patent office of each country in which the applicant wants patent protection, generally within 30 months of the earliest filing date.

The PCT provides two advantages. First, it delays the need to file costly foreign applications until the 30-month date, allowing an invention the opportunity to be further developed, evaluated and/or marketed for licensing. Second, the preliminary international examination simplifies the patent prosecution process by having a single examiner speak to the patentability of the claims. This can save significant costs in prosecuting foreign patent applications.

What is the timeline of the patenting process and resulting protection?

Currently, the average U.S. utility patent application remains pending for about two to six years. Once a patent is issued, it is enforceable for 20 or 21 years from the application's initial filing date.

Why does Boston Children's protect only some IP through patenting?

Some inventions may not need a patent filing as part of the commercialization strategy. The expense and the length of time required may make patent applications inadvisable for some Boston Children's inventions. Before investing in a patent filing, we carefully review the invention's commercial potential and patent landscape. However, because the need for commencing a patent filing usually precedes finding a licensee, we seek early protection for as many promising inventions as possible.

Who ultimately decides what gets patented?

Your assigned TIDO licensing manager will consult with you when making a patent filing decision, taking your input and the factors above into consideration. Based on the licensing manager's analysis and recommendations, TIDO's Senior Director ultimately makes the final decision as to whether to file a patent application or seek another form of protection.

Who pays the expenses of getting an invention patented?

The patenting process can easily cost tens of thousands of dollars for a U.S. patent and considerably more for international patents. Boston Children's pays for the patent expenses and manages the entire patenting process through TIDO. When an invention is licensed to a company, Boston Children's will arrange for the company to reimburse these expenses.

Will Boston Children's initiate or continue patenting activity without an identified licensee?

Boston Children's often accepts the risk of filing a patent application before a licensee has been identified. After Boston Children's rights have been licensed, the licensee generally pays the patenting expenses. At times, we must suspend further patent efforts if we have not identified a licensee after trying for a reasonable period of time or if it is determined that we cannot obtain appropriate patent protection. These decisions are made on a case by case basis.

8.

COPYRIGHTS

What is a copyright and how is it useful?

Copyright is a form of protection provided to the authors of “original works of authorship.” Unlike patents that protect an idea, copyright protects the specific expression of an idea, and the fixing of that idea in a tangible medium. At Boston Children’s, there are diverse examples of copyrightable works, including research articles, books, forms of all sorts, brochures, education material, handouts, fliers, excel tables, computer software, apps, websites, music, images, videos and others. Copyright protection is automatically secured when an idea is fixed into a tangible medium, as when written down in notebooks, published in a journal, captured as an image or written into software. The U.S. Copyright Act generally gives the copyright owner the exclusive right to conduct and authorize various acts, including copying, displaying, reproducing, translating, performing and making derivative works and distributing copyrighted works. Ownership of copyright is covered in the Boston Children’s Intellectual Property Policy.

As the owner of copyright, Boston Children’s can determine how the copyrighted works may be used by others and under what terms and conditions. Much of the copyrighted material generated at Boston Children’s is distributed free of charge as part of its teaching mission; examples include the general health care information on Boston Children’s website, research articles that are accessible online and many open-source software programs originated at Boston Children’s. In some cases, Boston Children’s may opt to charge for the use of Boston Children’s material, as when a commercial entity uses it for commercial purposes.

How is software IP protected?

Software code (source code) is protected by copyright once it is written. In addition, the software system and algorithm may be protectable by patents.

What is a copyright notice and how do I represent a proper Boston Children's copyright notice?

Copyright notices serve to inform the public of the source of the material and give information about how to contact the copyright holder for permission to copy the work. Correct copyright notices should be placed on material that is to be shared with others. This applies to images, presentations, papers, teaching materials, computer software, websites, brochures and other forms of expression. Below is the recommended format for marking a Boston Children's copyrighted work:

©[year created] Boston Children's Hospital. All Rights Reserved.
For permissions contact [name and/or title, department or division],
Boston Children's Hospital, 300 Longwood Avenue, Boston, MA 02115.
[you can give a phone number if you like]

What is a trademark or service mark and how is it useful?

Trademarks and service marks are ways to mark materials with a brand or logo to identify the source of the material and convey information about quality that may be associated with a brand. A trademark includes any word, name, symbol, device or combination of these that is used in commerce to identify and distinguish the goods of a manufacturer or seller from those of others and to indicate the source of the goods. A service mark is any word, name, symbol, device or combination of these that is used or intended to be used in commerce to identify and distinguish the services of one provider from those of others and to indicate the source of the services.

What is trademark registration?

Trademarks generally become protected as soon as they are adopted by an organization and used in commerce, even before registration. In fact, a trademark must be in use before it can be registered. Registration is then necessary to enforce the trademark (prevent others from using it). The U.S. Patent and Trademark Office is responsible for registering trademarks and will provide a determination of rights based upon legitimate use of the mark. With a federal trademark registration, the registrant is presumed to be entitled to use, and prevent others from using, the trademark throughout the U.S. for the goods or services for which the trademark is registered.

9.

MARKETING AN INVENTION

How does TIDO market my inventions? How can I assist?

TIDO's licensing managers and our Business Development and Marketing team use many sources and strategies to identify potential licensees and market inventions. The best way to start a marketing campaign is to leverage your existing relationships and those of the TIDO staff. TIDO also identifies prospective licensees through market research and pitches licensing opportunities to industry scientists and business development executives at partnering meetings. Once companies show interest, the inventor is the best person to fully describe the invention and its technical and competitive advantages. The most successful results in licensing and corporate research funding come when the inventor and the licensing professional work together as a team to market and pitch the technology or research.

How are most licensees found?

Many licensing leads are found through inventors' relationships with industry. Your own research and consulting relationships are often valuable sources, as are TIDO's relationships. We also cultivate contacts obtained from digital marketplaces, market research, industry networking events and existing licensing relationships.

How long does it take to find a potential licensee?

It can take months or years, depending on the invention's attractiveness, its stage of development, competing technologies and the size and intensity of the market. Most Boston Children's inventions tend to be in the early stage of the development cycle and will therefore require a substantial investment in translational development to attract a licensee, such as industry-sponsored research or a Technology Development Fund award.

10.

STARTUP COMPANIES

What is a startup company and why choose to create one?

A startup is a new business entity formed to commercialize one or more technologies. Forming a startup company is an alternative to licensing the IP to an established business. A few key factors when considering a startup company include:

- » expected business viability
- » product development risk (often companies in established industries are unwilling to take the risk)
- » the potential for multiple products or services from the platform technology (few companies survive on one product alone)
- » the startup's competitive advantage
- » the target market
- » potential revenues
- » interest of the inventor(s)

An increasing number of Boston Children's researchers have become interested in starting their own companies to commercialize inventions. If you are considering starting a company, discuss your business plans with your TIDO licensing manager. TIDO will work with you to determine the best way to get a company off the ground, advise you on many aspects of company formation and ensure that your intellectual property is protected. When the time is right, TIDO will negotiate with the company to execute a license or option agreement.

Who decides whether to form a startup company around a Boston Children's technology?

TIDO works with inventors and others to identify the most appropriate licensing partner or partners, whether established businesses or a new startup. Before launching or taking equity in the company, you will need approval from your chief or program director.

What assistance and resources are available to Boston Children's inventors?

Your TIDO licensing manager serves as a resource when you consider forming a startup company. TIDO may be able to provide help in locating prospective management talent, making introductions to potential investors, reviewing and advising you on business plans, developing a funding strategy and engaging experts to work on key gating issues. Boston Children's also offers technology development and startup resources such as the [Technology Development Fund](#) and the [Innovation and Digital Health Accelerator](#).

INVENTOR PROFILE

TIMOTHY SPRINGER, PHD
PROFESSOR OF MEDICINE,
PROGRAM IN CELLULAR AND
MOLECULAR MEDICINE

Springer is one of the most entrepreneurial researchers at Boston Children's. He discovered integrins and their ligands in the 1980s. His work has led to the characterization of the integrin structure and function. His findings have led to the founding of multiple startup companies, including LeukoSite, Scholar Rock and Morphic Therapeutic, as well as multiple approved therapeutics.



What role does an inventor usually play in a company?

Boston Children's faculty and employees typically serve as founders, Scientific Advisory Board members or in some other technical developmental capacity. Most faculty do not leave Boston Children's and join the startup company. In many cases, the startup investors and management team will identify the inventor's best role based on expertise and interests. As the company matures and additional investment is required, the inventor's role may change. Faculty involvement of any kind in a startup is reviewed by Boston Children's Office of General Counsel and the Conflict of Interest Committee.

How much of my time and effort will starting a company take?

Starting a company requires a considerable amount of time and effort. Often you will need to champion the effort and work with investors or entrepreneurs to form the business model and build up the opportunity. After the team is in place, time and effort is required for discussions with investors, carrying out company responsibilities and hospital administrative processes, such as Conflict of Interest reviews.

"BY LEVERAGING HOSPITAL RESOURCES AND INDUSTRY EXPERTISE, the Technology Development Fund is able to de-risk promising hospital technologies and facilitate partnerships with corporate entities and entrepreneurs to develop new products for patient care."

— **Monique Yoakim-Turk, PhD**
Partner, Technology Development Fund

Can Boston Children's or the inventor(s) accept equity in the company?

Inventors may accept equity in a startup in conjunction with a role as founder, consultant, Scientific Advisory Board member or other function. This requires written approval in advance from your chief or program director, the Office of General Counsel and TIDO.

Boston Children's also can accept equity as part of the financial terms of the license. Equity may be substituted for other cash considerations, which are often limited for startups. It is also a way for Boston Children's to share some of the risk associated with a startup. A decision to take equity must make sense for both Boston Children's and the company.

11.

LICENSE AGREEMENTS

What is a license?

A license is a legal contract granting certain permissions and rights from the licensor to the licensee in exchange for considerations. Boston Children's licenses usually relate to granting IP rights to companies in exchange for financial payments.

License agreements describe the licensee's rights and responsibilities related to the use of Boston Children's IP. These agreements usually stipulate that the licensee should diligently seek to develop the IP into products and services for the public good and provide a reasonable financial return to the hospital.

How is a company chosen to be a licensee?

A licensee is chosen based on its ability to develop the technology for the benefit of the general public. Sometimes, an established company with experience in similar technologies and markets is the best choice. In other cases, the focus and intensity of a startup company is a better option.

What is the relationship between an inventor and a licensee?

Many licensees require the inventor's active assistance in the early stages of commercial development. This help can range from infrequent informal contacts to a more formal consulting relationship. Working with a new business startup can require substantially more time, depending on your role in or with the company and your continuing role at Boston Children's. Your participation with a startup, even as a consultant, is governed by Boston Children's Conflict of Interest Policies and the approval of your supervisor.

What other types of agreements pertain to commercialization?

- » Confidential Disclosure Agreements (CDAs) protect the patentability of an invention during evaluation by potential licensees. CDAs also protect proprietary information of third parties, which is needed to conduct research or to evaluate research opportunities.
- » Material Transfer Agreements (MTAs) describe the terms for sharing biological materials with labs outside Boston Children's, typically for research or evaluation purposes. MTAs often cover rights to IP arising from work done with shared materials. These IP rights can be endangered if materials are used without a proper MTA.
- » Option Agreements, or Option Clauses within research agreements, reserve the opportunity for a third party to negotiate a license for IP. Option Clauses are often provided in a sponsored research agreement with corporate research sponsors or option agreements are entered into with third parties wishing to evaluate a technology before entering into a full license agreement.
- » Sponsored Research Agreements describe the terms under which sponsors, such as a biotech company, provide research support to the hospital.

All of the above agreements are negotiated and administered by TIDO.

INVENTOR PROFILE

STUART ORKIN, MD
ASSOCIATE CHIEF, DIVISION
OF HEMATOLOGY/ONCOLOGY

Orkin first cloned the gene for von Willebrand factor (vWF) in 1985, which led to the development of Vonvendi, a treatment for von Willebrand disease that was FDA approved in 2015.



12.

COMMERCIALIZATION

What activities occur during commercialization?

Most licensees continue to develop an invention to enhance the technology, reduce business risk, prove efficacy and satisfy regulatory and market requirements for adoption by customers. This can involve additional product testing, prototyping for manufacturability, durability and integrity and further development to improve performance and other characteristics.

What is my role during commercialization?

Your role can vary depending on your interest and willingness to be involved. If you are an inventor on the patent, you need to participate in the patenting process, including executing various legal documents. You may have further involvement, such as consulting or advisory roles with the licensee.

What revenues are generated for Boston Children's if commercialization is successful?

Boston Children's asks for financial compensation from its licensees, in line with industry best practices; however, each deal is unique and varies depending on specific factors. Most license agreements include an upfront payment and subsequent annual payments, as well as a royalty on sales of the product. Startup licenses may include equity as partial compensation. It can take many years for technologies to reach the market and early compensation is often modest. All revenue received by Boston Children's is distributed according to the Boston Children's Intellectual Property Policy. See [page 36](#) for Boston Children's revenue distribution details.

What happens if the startup company or licensee is unsuccessful in commercializing my invention?

Developing early-stage technologies is risky and many efforts do not succeed. Most Boston Children's license agreements include performance milestones that the licensee must meet. Not meeting these milestones can result in termination of the license agreement. This gives Boston Children's the opportunity to get the technology back from the licensee and could lead to another attempt at developing the technology.

13.

NAVIGATING CONFLICTS OF INTEREST

How does Boston Children's define a conflict of interest?

A conflict of interest can occur when hospital employees or their family members have a relationship with an outside organization that puts them in a position to:

- » influence the hospital's business, research or other areas that could lead to direct or indirect financial gain
- » compromise the scientific integrity of one's research
- » provide improper advantage to others to the disadvantage of Boston Children's

When should I seek guidance on a conflict of interest?

The Conflict of Interest Committee reviews situations in which involvement with a company could be seen to influence the impartiality of your research. These can include holding equity in a company that is commercializing your research or being on the Scientific Advisory Board of a company sponsoring a clinical trial.

What is a conflict of commitment?

A conflict of commitment may exist if duties, assignments or responsibilities associated with a technology license or outside business arrangement have a negative impact on your ability to meet commitments associated with your Boston Children's employment or exceed the amount of time available to you for these activities. The best approach is to fully disclose your situation to your supervisor and discuss the implications for your job responsibilities.

How does Boston Children's manage conflicts associated with research and technology transfer transactions?

If there is a conflict, Boston Children's Compliance Office and Conflicts Committee will set up a management plan to provide oversight. Before accepting equity in a startup, you will need to meet with the Conflicts Committee.

For more information on conflicts of interest

Office of the General Counsel

web2.tch.harvard.edu/generalcounsel

Conflict of Interest Manual

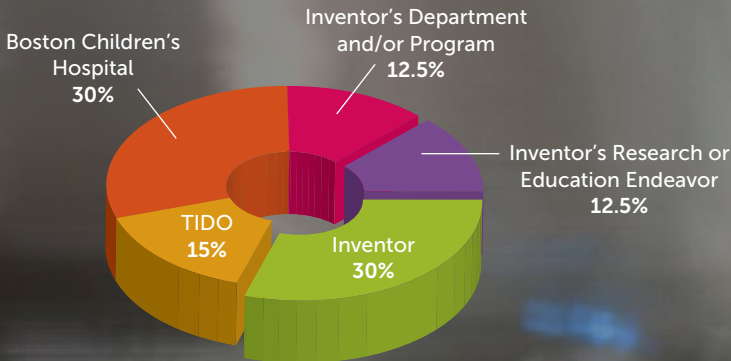
web2.tch.harvard.edu/compliance

14.

REVENUE DISTRIBUTION

What can I expect to gain if my IP is licensed?

Per Boston Children's Intellectual Property Policy, any revenue Boston Children's receives from the licensing of an invention will go to paying back expenses incurred by Boston Children's, such as patent filing, licensing and litigation costs, and any money owed to third-party sponsors, co-owners or co-inventors. For inventions licensed after January 15, 2015, the rest of the revenue Boston Children's receives will be distributed as follows:



What are the tax implications of any revenues I receive from Boston Children's?

License revenues are typically taxed as Form 1099 income. You should consult a tax advisor for specific advice.

How are inventor revenues distributed if there are multiple inventors or inventions in a license?

The inventor's share is divided evenly among all the inventors, unless all inventors agree to an alternative split in writing.

How is equity from a license distributed?

When Boston Children's equity is liquidated (through an Initial Public Offering or acquisition of a company), the resulting funds are distributed in accordance with the Boston Children's Intellectual Property Policy.

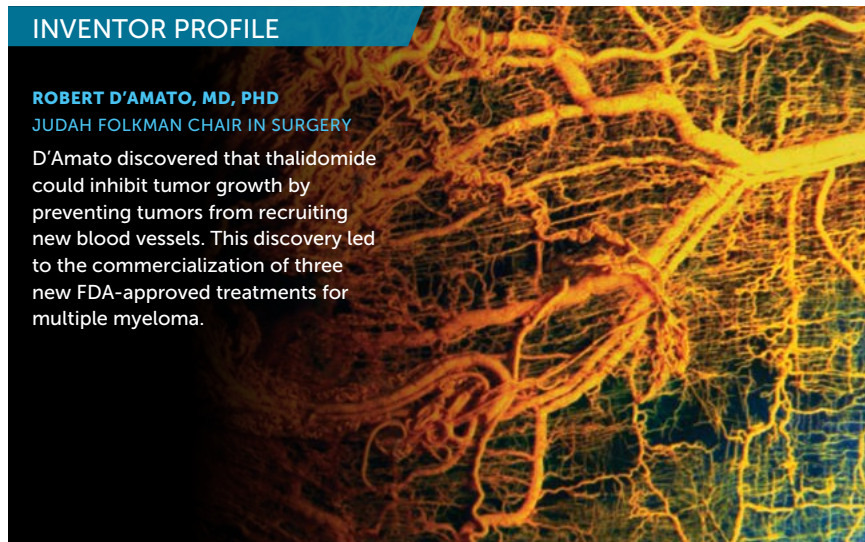
What if I leave Boston Children's?

The inventor's share will still be paid to you. In the event of death, the inventor's share will be paid to your estate. All other shares remain with Boston Children's.

INVENTOR PROFILE

ROBERT D'AMATO, MD, PHD
JUDAH FOLKMAN CHAIR IN SURGERY

D'Amato discovered that thalidomide could inhibit tumor growth by preventing tumors from recruiting new blood vessels. This discovery led to the commercialization of three new FDA-approved treatments for multiple myeloma.



15.

REINVESTMENT AND RELATIONSHIPS

Every year, TIDO, working with Boston Children's inventors and business partners:

- » assists with approximately 150 new invention disclosures
- » executes more than 30 option and license agreements
- » negotiates more than 40 corporate sponsored research and collaboration agreements
- » assists in forming two to four new startup companies

The revenues generated through these activities are shared among Boston Children's departments, laboratories, inventors and partnering institutions. Much of these revenues are reinvested in additional research, helping support the next generation of research, researchers and entrepreneurs.

In addition to generating revenues, these activities create and deepen relationships that support our hospital missions. They often spawn additional research projects and collaborative investments, enhancing the hospital's ability to bring new therapies to patients worldwide.

INVENTOR PROFILE

RICHARD MALLEY, MD KENNETH MCINTOSH CHAIR IN PEDIATRIC INFECTIOUS DISEASES

The Multiple Antigen Presenting System (MAPS) bridges the gap between whole cell and acellular vaccines to create a vigorous immune response and lower the risk of side effects. Startup Affinivax was launched to commercialize the vaccine platform.



ABOUT BOSTON CHILDREN'S HOSPITAL

Boston Children's promotes the advancement of scientific knowledge and discoveries through teaching, research and other means. At the same time, the hospital encourages researchers and clinicians to develop their discoveries and innovations into products and services that benefit the public by supporting inventorship, intellectual property development, entrepreneurship and commercialization.

ABOUT THE TECHNOLOGY AND INNOVATION DEVELOPMENT OFFICE

The mission of the Technology and Innovation Development Office (TIDO) is to maximize the impact of Boston Children's innovations on patient health while enhancing the research endeavor. TIDO is composed of specialists in licensing, patenting, business development, marketing and legal matters. We manage Boston Children's intellectual property, including drugs, devices, research tools and digital health technologies, and are responsible for the evaluation, protection, development and commercialization of these inventions. We also negotiate and execute all corporate collaboration, sponsored research and material transfer agreements.



**Boston
Children's
Hospital**

Until every child is well™

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